## DETAILED ACTION

Applicant's remarks filed 25 November 2009 are acknowledged and entered.

### *Status of Claims*

Claims 1-17 are cancelled.  Claims 18-34 are currently pending and under consideration.

### *Withdrawn Rejections/Objections*

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn because of the arguments filed 25 November 2009. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims 26-33 are drawn to a method of confirming a validity of result of clinical examination of a part of a subject for a clinical examination.  The instant claims are drawn to the abstract process steps of receiving present and previous data, storing a plurality of reference patterns, selecting a reference pattern matching the present data and previous data, calculating a value indicative of a distance between a

position between the reference patterns in the reference patterns and determining a

validity of the present data based on the value.

The en banc decision regarding Bilski v. Warsaw (2008) set forth that a process

is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it transforms a

particular article into a different state or thing. See in re Bilski 88 USPQ2d 1385 (Fed.

Cir. 2008) and in re Comiskey 89 USPQ2d 1655 (Fed. Cir. 2009). See also Benson,

409 U.S. at 70; Diehr, 450 U.S. at 192; see also Flook, 437 U.S. at 589 n.9; Cochrane v.

Deener, 94 U.S. 780, 788 (1876).

The instant method claims 26-33 do not recite or inherently involve

transformation of any particular article into a different state or thing. Instant claims 26-

33 do not recite any limitation that ties the recited abstract process to any particular

machine or apparatus.

Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining,

See Ex parte Langemyr (May 28, 2008). Applicants are cautioned against introduction

of new matter in an amendment.


Claims 18-25 recite a "device for confirming a validity of result..." comprising "a

receiving unit configured to receive", "a storing unit configured to store", "a selecting unit

configured to select", "a calculating unit configured to calculate" and "a determining unit

configured to determine".

The specification on pages 10-14 discloses relationships of the units with

functions, there are no hardware necessarily associated with the above units. It is

noted that while the specification provides EXEMPLARY embodiments of some

"hardware" aspects of the inventive device, the disclosure of; for example, a hard disk

drive as a storage "unit," are exemplary only and do not limit the claims to such

embodiments. Thus at least one embodiment of the invention may be implemented by

software. Thus, the "units configured to" perform particular functions, recited in claim 18

encompass software (a program) only. Software may be in the form of a transient

carrier wave or signal, and thus is not statutory

### *Response to Arguments*

Applicant's arguments filed 25 November 2009 have been fully considered but

they are not persuasive.

Applicant argues that the device recited in claims 18-25 is a product, therefore

the claims to not apply to the Bilski tie to a particular machine or transformation of a

particular article. Applicant argues that one skilled in the art would recognize that the

limitation "storing unit" comprises a hardware component for storing information.

In response to applicant's argument that the instant device is a product and not

applicable to the test under Bilski, is correct but moot. Applicant's instant device,

despite the "storing unit" limitation, encompasses software only. While there are non-

limiting embodiments described in the specification, the "units" recited in the instant

claims maybe reasonably interpreted as merely software. For instance, the recited

"storing unit" can be interpreted as software that, when executed, drives the process of

storing data.

Applicant similarly argues the "storing" limitation in the instant method claims 26-33, would be recognized as a storing step involving a particular machine, thus satisfying the test recited in Bilski.

In response to applicant's argument that the limitation "storing" would be recognized as involving a particular machine is not correct. The limitation "storing a plurality of reference patterns" is considered insignificant extra solution activity that bears is not required to perform the critical aspects of the invention. There is no tie to a particular machine or apparatus by the recited limitation.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.    Determining the scope and contents of the prior art.
2.    Ascertaining the differences between the prior art and the claims at issue.
3.    Resolving the level of ordinary skill in the pertinent art.
4.    Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 19, 21-27, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiba et al. (EP 0389992) in view of Geva et al. (US 2004/0073098).

The instant claims are drawn to a method of confirming a validity of result of clinical examination of a part of a subject for a clinical examination comprising the steps of receiving present and previous data in time, storing a plurality of reference patterns, selecting a reference pattern matching the present data and previous data in the reference patterns, calculating a value indicative of a distance between a position between the reference patterns and determining a validity of the present data.

Regarding claims 18, 22, 26, 30 and 34 Toshiba shows a method and apparatus for analyzing the validity of medical examination data, (page 2, lines 27-40; Figures 1-2). Toshiba shows receiving thousands of sets of present and previous medical examination data with corresponding teaching data stored in order of acquisition (time), (page 4, lines 30-33), medical examination data and teaching data associated with a group (pattern) (page 5, lines 10-28). Toshiba shows calculating a value indicative of whether the medical examination data is valid or if the medical examination data should

be obtained again by re-examination based on previous data (i.e. judgments learned at the initial learning of the neural network, (page 4, lines 6-26).

Toshiba does not show reference patterns classified into a plurality of levels, first pattern best matching with present data and second reference best matching with previous data or calculating a distance between a position of the first and second reference patterns.

Geva et al. shows a method that obtains a patient's specific heartbeat pattern, corresponds the patient's pattern with a particular reference heartbeat pattern from a plurality of heartbeat patterns and utilizes additional new heartbeat patterns for re-averaging the person's unique viable heartbeats according to predetermined criteria, (paragraphs 17, 18, 29, 30, 98-105).  Geva et al. also shows an Adaptive Segmentation Algorithm for EEG signals (ASAEEG) algorithm that partitions EEG signal into Quasi-Stationary Segments (QSSs), wherein the ASAEEG algorithm utilizes the Generalized Likelihood Ratio (GLR), for distinguishing between statistically QSSs, e.g. for two time series, outputs a value which represents the statistical difference (distance) between the two series, (paragraph 174).  QSSs are clusters of data (patterns), (paragraphs 189-190).  Geva et al. shows software for executing steps of the method, (paragraphs 97-105).

Regarding claims 19, 27, Toshiba shows each set of medical examination data corresponding to a specifically modified teaching data, (page 4, lines 30-57).

Regarding claims 21 and 29, Geva et al. shows waveform data, (paragraph 108, Figure 11).

Regarding claims 23, 31, Toshiba displays when the medical examination data does not meet a particular value and there is a need for a re-examination, (page 4, lines 19-26).

Regarding claims 24, 32, Toshiba shows stored groups of teaching data that correspond to a particular group of medical examination data, (page 5, lines 19-28).

Regarding claims 25, 33, Toshiba shows stored ranges of values that the value of the medical examination data corresponding teaching data can be compared, (page 6, lines 27-33).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method and system of confirming a validity of result of clinical examination of a part of a subject for a clinical examination by Toshiba with the comparison and classification levels in the method and system of analysis of biomedical signals of a patient by Geva et al. because Geva et al. shows analysis of several physiological signals and introduce to a clinician already-correlated data so as to eliminate artifacts, noise, etc. to provide more accurate and well characterized selected physiological events and save the clinician analyzing/interpretation time, (paragraph 5).

Claims 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiba et al., (EP 0389992) in view of Geva et al. (US 2004/0073098) as applied to claims 18, 19, 22-27, 30-34 above, in view of Ioki et al. (Japan Association of Medical Information, 2002, 14 November, 211-213), IDS, received 11 January 2006.

The instant claims 20 and 28 depend from claims 18 and 26 respectively, with the extra limitation that the reference patterns include image data.

Toshiba et al. in view of Geva et al. is applied to claims 18, 19, 21-27 and 29-34 above.

Toshiba et al. in view of Geva et al. does not show reference patterns that include image data.

loki et al. teaches that 90% of cases with allergic dermatitis belonged to the pattern in which the eosinophil area shifted to the left in the scattergram image, (abstract; Figure 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method and system of confirming a validity of result of clinical examination of a part of a subject for a clinical examination made obvious by Toshiba and Geva et al. by the analysis of patterns of eosinophils in scattergram images of loki et al. because Toshiba shows the importance of obtaining differing groups of teaching data that correspond with different types of medical examination data, (page 5, lines 10-18) and a person of ordinary skill in the art would recognize that images of data may provide recognizable patterns of the data, thus providing an analysis technique useful for diagnosis and analysis of pathogenesis of various diseases (loki, abstract). Therefore, one of ordinary skill in the art would recognize the claimed process as a combination of routine applications that are well known the art that and produce no more than expected results.

## *Response to Arguments*

Applicant's arguments filed 25 November 2009 have been fully considered but they are not persuasive.

Applicants argue that neither Ohhashi (Toshiba) or Geva disclose or suggest the recited "calculating unit" or the "step of calculating a value indicative of a distance between a position of a first reference pattern and a position of the second reference pattern in the reference patterns". Applicants argue that Ioki does not remedy the deficiencies of Ohhashi (Toshiba) and Geva.

In regards to applicant's argument that Geva does not disclose or suggest a "calculating unit" or the "step of calculating a value indicative of a distance between a position of a first reference pattern and a position of the second reference pattern in the reference patterns", Geva teaches the ASAEEG algorithm, or "calculating unit" that calculates a value representing the statistical difference (distance) between two different patterns (QSSs) at two time series (two positions).

In response to applicant's argument that Ioki does not remedy the deficiencies of Toshiba or Geva, regarding claims 18-34, as the examiner maintaims that Geva does teach a calculating unit for the reasons set forth above, he also maintains that Toshiba in view of Geva in view of Ioki make obvious the limitations of the instant claims.

## *Conclusion*

No claims are allowed.

   **THIS ACTION IS MADE FINAL.**  Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

   A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action.  In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action.  In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to LARRY D. RIGGS II whose telephone number is

(571)270-3062.  The examiner can normally be reached on Monday-Thursday, 7:30AM-

5:00PM, ALT. Friday, EST.

   If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Marjorie Moran can be reached on 571-272-0720.  The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
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